

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

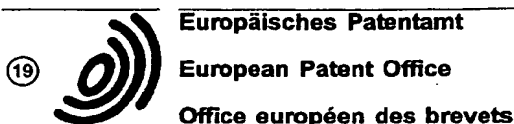
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.



①1 Publication number : **0 573 275 A2**

①2 **EUROPEAN PATENT APPLICATION**

②1 Application number : **93304272.3**

⑤1 Int. Cl.⁵ : **A61N 1/05**

②2 Date of filing : **02.06.93**

③0 Priority : **02.06.92 US 892463**

④3 Date of publication of application :
08.12.93 Bulletin 93/49

⑧4 Designated Contracting States :
CH DE DK FR GB IT LI NL SE

⑦1 Applicant : **SIEMENS AKTIENGESELLSCHAFT**
St Martin Strasse 76
D-81541 München 2 (DE)

⑦2 Inventor : **Helland, John R.**
22706 Coral Way
Santa Clarita, CA 91350 (US)
Inventor : **Muff, Diane F.**
10618 Dempsey Avenue
Granada Hills, CA 91344 (US)

⑦4 Representative : **Rees, David Christopher et al**
Kilburn & Strode 30 John Street
London WC1N 2DD (GB)

⑥4 **High efficiency tissue stimulating and signal sensing electrode.**

⑤7 A pacing lead (20) having a porous electrode of platinum-iridium with recessed areas of grooves (62) formed in the surface. The grooves (62) allow for acute electrode stabilisation as a result of clot formation and endocardial tissue capture during insertion and immediate immobilisation upon implant. At least one layer of porous coating of 20 to 200 μ m diameter spherical particles (70) is deposited on the surface of the base electrode (36) to obtain a porous macrostructure form promoting chronic tissue ingrowth. Additionally, a microstructure surface coating is applied to increase the active surface area and enhance electrical efficiency by lowering electrochemical polarisation and increasing electrical capacitance.

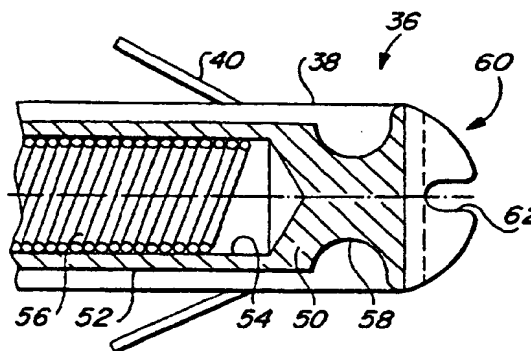


FIG. 2

EP 0 573 275 A2

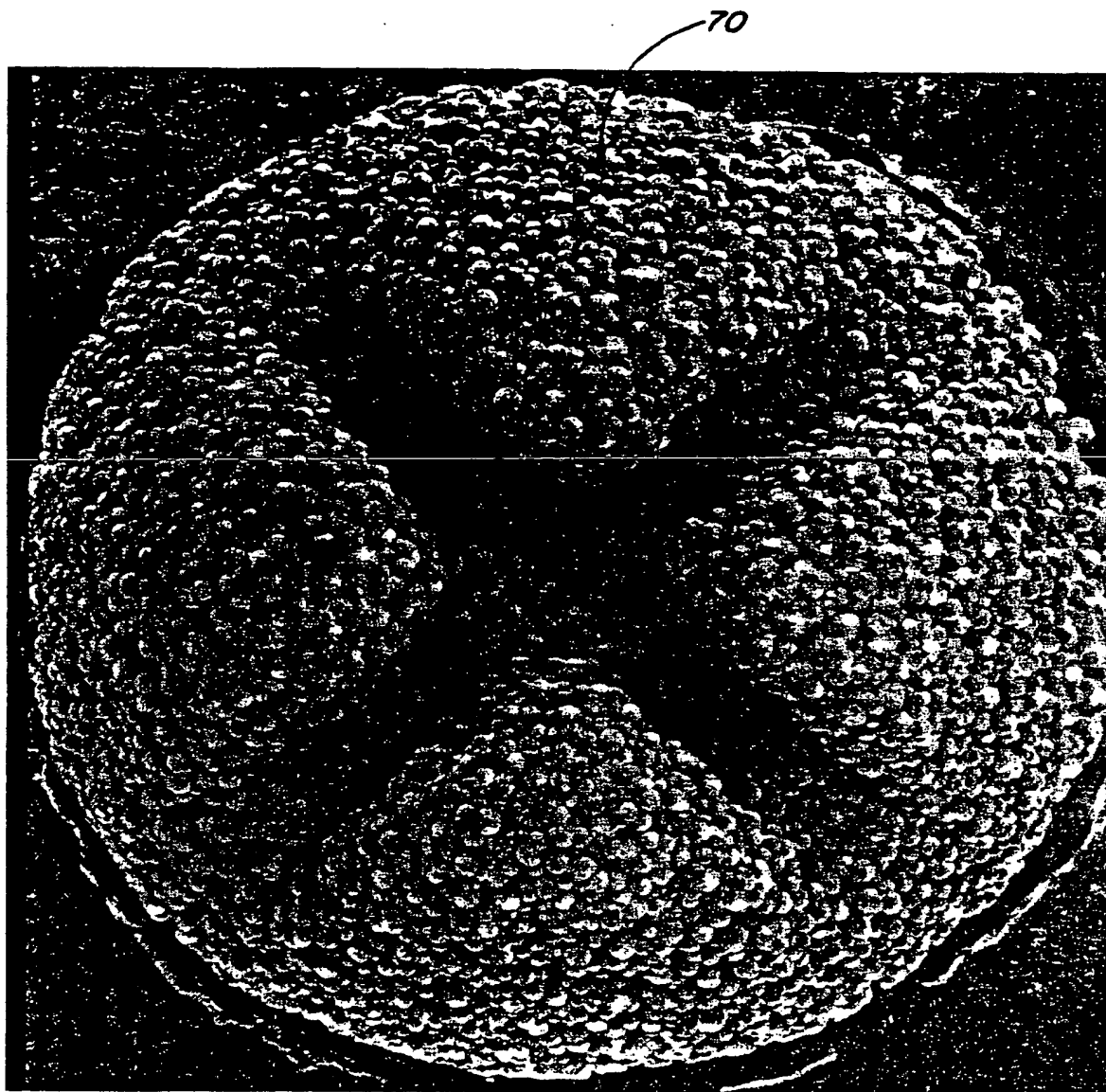


FIG. 4

This invention relates generally to an implantable pacing lead and more specifically to a pacing lead having a high efficiency tissue stimulating and signal sensing porous electrode for use with a cardiac pacemaker and a method for making the porous electrode.

For a cardiac pacemaker, implant lifetime is determined by the energy delivered per pulse. The pacemaker will have a longer life if the energy delivered per pulse is maintained at a minimum. Alternatively, the energy can also be used to provide for more features in the pacemaker. The design of an implantable pacing lead which is used with the pacemaker is influenced by the optimum signal for pacing stimulation. Physiologically, a cardiac pacemaker must be capable of generating a signal with a sufficient magnitude to depolarize the excitable cells of the endocardium. The electrode size, material, surface nature, and shape; the body tissue or electrolyte conductivity; and the distance separating the electrode and the excitable tissue, combine to determine the energy required of the pacemaker. Accordingly, the main factors to be considered with regard to the design of implantable pacing lead's electrode are: the size, surface nature, material and shape; the fixation of the electrode to the tissue; and the endocardial tissue reaction.

In selecting a pacemaker, the current drain, and therefore the implant lifetime, is determined by the impedance to pacing pulses. The pacemaker lead's electrode must be capable of delivering a pacing pulse with a pulse width generally in the range of 0.01-2.0 milliseconds and 0.5 to 10.0 volts to the tissue, and to also sense and transmit a QRS signal arising in the atria and ventricles of the heart to the pacemaker circuitry. Generally, the electrode-electrolyte system impedance is higher for sensing than for pacing. Pacing leads for pacing and sensing in the atrium, which can exhibit different stimulation and depolarization parameters than the ventricle, are also required.

The electrode-endocardial tissue system impedance characteristics may be understood in terms of an interface component and a spreading resistance component. The interface component occurs within a few microns of the surface of the electrode. The spreading resistance component depends predominantly on the tissue resistivity. Generally, the former reflects the charge transfer characteristics of the electrode-tissue interface influenced mostly by the surface area and material of the electrode, and the latter reflects the overall size and shape of the electrode; the surface nature of electrode; and the resistivity of the tissue.

The current drain of a pacemaker is determined by the impedance of the pacemaker circuitry, the nature of the electrode lead resistance, and the characteristics of the electrode tip interface with the electrolyte system. For a given pacemaker circuit and elec-

trode lead design, the current drain is well defined. Thus, the nature of the electrode-endocardial tissue interface determines the overall current requirements of the system.

As an additional design factor, the most significant frequency of the pacing pulse is of the order of 1 KHz. At this frequency, the interface impedance is small and most of the impedance to the pacing pulses is due to the bulk or spreading impedance. This is determined by the shape and size of the electrode tip and is generally inversely related to the radius of the electrode tip.

The most significant frequency components of a signal to be sensed, i.e., the ventricular QRS, are in the bandwidth of 20-100 Hz. In this region, the interface impedance of the sensed signal becomes the most significant. The interface impedance is determined in large part by the microsurface area of the electrode tip and develops within a few microns of the surface. As described herein, the microsurface area of a porous electrode tip is the wettable surface, area which includes all of the exposed and interstitial porosity surfaces of the electrode tip.

As a final design consideration, it has been determined that the pacing or stimulation threshold is a reflection of the electrical energy required for a pulse to initiate a cardiac depolarization. The stimulation threshold typically rises for a period of a few weeks after the implant of a cardiac pacemaker generally as a result of an increase in the spacing between the electrode and the excitable tissue. The increase occurs due to the development of a fibrous capsule around the electrode tip. The thickness of the fibrous capsule is generally dependent upon the mechanical characteristics of the distal end of the lead (i.e., stiff or flexible); the geometry of the electrode tip; and the microstructure of the electrode tip, such as a porous electrode surface and the electrode material itself. In this regard, the environment of the endocardium must be considered. Specifically, the constant beating of the heart can cause the electrode to pound and rub against the endocardium, causing irritation and a significant subsequent inflammatory response, which ultimately results in healing, and the development of a fibrotic tissue capsule about the electrode tip. Also, a rough surface microstructure or one with sharp protrusions for the electrode will tend to be abrasive or traumatic on the abutting heart cells, also causing irritation, which also tends to cause the development of a thicker fibrotic capsule.

In view of the above characteristics of an electrode and its implantology issues for a cardiac pacemaker, it is clear that an electrode tip with a small geometric surface area (resulting in higher pacing impedance) will have a low current drain. However, in order to enhance sensing, the same electrode tip should have a large microsurface area and be of such a material to result in a low polarization and high capaci-

tance which, in turn, results in a low sensing impedance and improved sensing. A cardiac pacemaker electrode tip that is constructed to be porous is therefore preferred in order to best satisfy these requirements.

In a pacemaker electrode, minimal tissue reaction is desired around the tip, but firm intimate attachment of the electrode to the tissue is essential to minimize any electrode movement relative to the abutting tissue. A porous electrode tip with macro tissue entrapping structure allows rapid fibrous tissue growth into a hollow area or cavities in the electrode tip to facilitate and enhance attachment of the electrode to the heart. A reduced lead dislodgement rate is also expected as a result of such tissue ingrowth. A further aspect of importance is selection of porosity size, which must be such as to accommodate economical construction techniques, overall dimensional tolerances, and tissue response constraints.

According to the invention, there is provided an implantable lead for use with a cardiac pacemaker comprising an electrical conductor having an outer insulating sheath, an electrical connector coupled to the proximal end of the conductor and an electrode coupled to the distal end of the conductor, characterised in that the electrode has an electrode tip macrostructure geometry defining at least two plateau sections separated and the recessed groove section including surfaces having affixed thereto at least one layer of generally spheroidal conductive particles coated with a layer of nonmetallic material.

Preferably, the conductive particles have diameters ranging from 10 to 200 μm , and are configured in at least one layer on the electrode surfaces to provide interstitial porosity for tissue ingrowth. Suitable materials include platinum, titanium, palladium, platinum iridium and carbon.

It may be that the electrode tip includes two recessed areas configured to intersect one another thereby defining a cross shape; or includes at least two parallel aligned recessed areas defining at least three generally aligned plateau areas, the corners of these plateau areas such defining an angle of at least sixty degrees, or includes at least two sets of multiple, parallel aligned, recessed areas, configured to have the multiple aligned recessed areas of the sets intersecting one another.

Preferably, the groove profile defined by a depth of between 0.1 and 1.0 millimetres, a width of between about 0.2 and 1.5 millimetres, and each edge of the groove is optionally radiused with a radius of curvature of between about 0.001 and 0.5 millimetres.

Suitable non-metallic materials include titanium nitride, iridium oxide, titanium oxide, platinum oxide, palladium oxide or an activated form of carbon. Preferably, the layer of non-metallic material has a surface morphology which results in a porosity of greater

than about fifty percent.

The invention also extends to a method of forming an implantable lead for use with a cardiac pacemaker which comprises covering an electrical conductor in an insulative sheath, coupling an electrical connector to the proximal end of the conductor and coupling an electrode to the distal end of conductor, characterised by: forming the electrode tip macrostructure geometry to define at least two plateau sections separated by at least one recessed groove section; affixing to the plateau sections and the recessed groove section a plurality of generally spherical conductive particles; and coating the particles with a layer of non-metallic material preferably selected from titanium nitride, palladium, platinum oxide, iridium oxide, and activated carbon.

Preferably, the conductive particles are coated by vapour deposition, sintering, electroplating and electrode sputtering, preferably to a thickness of 20 to 30 μm . They may be affixed to the electrode distal tip by powder sintering, laser fusion, welding, injection moulding, or casting, and are preferably affixed in a series of successive steps in which a portion of the particles are affixed in each successive step.

The pacing tip electrode of the preferred embodiment of the present invention is a five square millimeter platinum-iridium (90%/10%) porous electrode with recessed areas or slots in the shape of a cross formed into the surface. The grooves allow for acute electrode stabilization tissue ingrowth as a result of naturally occurring clot formation during insertion and helps result in immediate immobilization of the electrode upon implant. A porous coating of 20-80 μm (micron) diameter spherical platinum-iridium (90%/10%) particles are deposited on the surface of the base electrode to obtain a porous macrostructure for chronic tissue ingrowth and also for extending the active surface area. Preferably, the particles are deposited in a two-step process where the first layer of particles is made up of 40 to 80 μm spheroidal particles. The second layer is made up of 20 to 40 μm spheroidal particles. The result is a clumping of the particles producing a uniformly textured surface with randomized particle attachment. Chronic tissue ingrowth into this clumped, porous macrostructure enhances the electrode stabilization.

The additional microstructure surface coating is applied on these particles to increase the active surface area and enhance electrical efficiency by lowering polarization and increasing electrical capacitance. The macrostructure is preferably created by sintering the platinum-iridium particles to the platinum-iridium electrode tip. The microstructure coating is preferably created by reactive sputtering of titanium nitride onto the platinum-iridium particles.

In its broadest sense, the invention is considered to extend to an implantable pacing lead for use with a cardiac pacemaker comprising: an electrical con-

ductor having a proximal end and a distal end; an insulative sheath covering said conductor; an electrical connector affixed to said proximal end of said conductor; and an electrode assembly affixed to said distal end of said conductor, said electrode assembly including a porous electrode distal tip having a polarisation index PI which is less than 100 mV/mm².

Preferably, the distal tip further comprises means for capturing blood cells during insertion of said electrode assembly into a human recipient, and for promoting clot formation and endocardial tissue capture thereof to aid fixation of said electrode distal tip to endocardial tissue; means for providing interstitial porosity and for increasing surface area of said electrode distal tip; and coating means for enhancing the electrical characteristics of said electrode distal tip, for increasing the electrical capacitance, and for reducing electrochemical polarisation at the electrode-endocardial tissue interface during pacing use.

Preferably, means for capturing blood cells and endocardial tissue and promoting clot formation and tissue ingrowth comprises: at least one recessed area traversing said electrode distal tip, said recessed area having a generally U-shaped profile defined by generally vertical walls and a base, said base of said recessed area having a transverse profile shape selected from the group consisting of semi-hemispherical, flat and concave. Preferably, the means for providing interstitial porosity and increasing surface area comprises: a plurality of generally smooth surfaced spheroidal particles affixed to the surface of said electrode distal tip including said walls and base of said at least one recessed area.

Preferably, the coating means comprises: a surface coating applied to the surfaces of said distal tip electrode and said spheroidal particles, thereon, said surface coating comprising a microscopically thin layer of a non-metallic material selected from the group consisting of titanium nitride, titanium oxide, carbon, iridium oxide, and platinum oxide, said surface coating applied by a process selected from the group consisting of sintering, vapour deposition, electroplating and sputtering.

The invention may be carried into practice in various ways and some embodiments will now be described by way of example with reference to the accompanying drawings, in which:-

Figure 1 is a side view of a pacing lead according to the present invention;

Figure 2 is a cross-sectional view of the distal tip of the electrode of the lead shown in Figure 1;

Figure 3 is an end view of the distal tip of the electrode of the lead shown in Figure 1 and;

Figure 4 is an electron microscope photograph of the distal tip of Figure 3, magnified by a factor of 50;

Figure 5 is an electron microscope photograph of part of the distal tip of Figure 3, magnified a factor

of 500;

Figure 6 is an electron microscope photograph of part of the distal tip of Figure 3, magnified by a factor of 8000.

Figure 7 is a graph of the pacing threshold performance of an electrode constructed according to the present invention;

Figure 8 is a graph showing cardiac signal sensing for an electrode according to the present invention;

Figure 9 is a cross-sectional view of an alternative configuration for the distal tip of Figure 1;

Figure 10 is an end view of an alternative tip configuration of Figure 9.

Figure 11 is a cross-sectional view of a second alternative configuration for the distal tip of Figure 1;

Figure 12 is an end view of the alternative tip configuration of Figure 11;

Figure 13 is a cross-sectional view of a further alternative configuration for the distal tip; and

Figures 14 and 15 schematically depict top and side views respectively of the microporous surface structure.

Figure 1 is a side view of a pacing lead 20 according to the present invention. The lead 20 is provided with an elongate lead body 22 which includes electrical conductors (not shown) covered with an insulation sheath 24. The insulation sheath is preferably fabricated of silicone rubber, polyurethane or some other suitable biocompatible, biostable polymer. At the proximal end 26 of the pacing lead 20, there is a connector assembly 28, which is provided with sealing rings 30 and which carries at least one electrical connector pin 32, and may also carry an anode terminal ring electrical connector 33. The connector assembly 28 is constructed using known techniques and is preferably fabricated of silicone rubber, polyurethane or some other suitable polymer for insulating. The connector pin (or pins for bipolar or multipolar leads) 32 and connector 33 are preferably fabricated of stainless steel or some other suitable conductive material.

At the distal end 34 of the pacing lead 20, there is an electrode assembly 36 which is discussed in more detail below. Immediately behind the distal end of the electrode assembly 36, there is a tine sheath 38 which includes a plurality of individual flexible tines 40. The tines 40 engage endocardial tissue and urge the electrode assembly 36 into contact with the endocardium, in a direction parallel to the axis of the electrode assembly 36. The tines 40 are more fully described in U.S. Patent No. 3,902,501. A fixation or lead anchoring sleeve 42, slidably mounted around the lead body 22, serves to stabilise the pacing lead 20 at the site of venous insertion by means of suture ties about the sleeve and underlying fascia.

The electrode assembly 36 of Figure 1 is shown in greater cross-sectional detail in Figure 2. As illu-

strated, the electrode assembly 36 includes a conductive electrode 50 as well as the tine sheath 38 and the tines 40 thereof. The conductive electrode 50 is preferably a unitary construction including, at its proximal end, a cylindrical portion 52 defining an axial bore 54. A coil-wound conductor 56 of the lead body 22 is inserted into the axial bore 54 and affixed in electrical contact thereto, for example, by mechanical crimping or welding. Proceeding toward the distal end of the conductive electrode 50, the conductive electrode 50 includes a neck area 58 having a reduced diameter from the cylinder 52 which provides a recessed area into which an interior extending ridge of the tine sheath 38 is inserted to provide positive engagement of the tine sheath 38 with the conductive electrode 50. Finally, the conductive electrode 50 terminates at an electrode distal tip 60.

As shown in Figure 2, the electrode distal tip 60 has a generally mushroom shape, such that the electrode distal tip 60 has a part hemispherical surface which is intended to provide electrical contact with the endocardial tissue. It should be appreciated that the electrode distal tip 60 may define a number of different profiles, from hemispherical to essentially planar with rounded edges. As shown in Figure 2 and more specifically in Figure 3, the electrode distal tip 60 includes at least one and preferably two or more recessed areas or grooves 62. The grooves 62 define generally pie-shaped segments shown in Figure 3. These pie-shaped segments of the electrode distal tip 60 will be generally referred to as the plateaux 64 in this specification, although it is recognised that the plateaux may be part hemispherical in shape, or may have other configurations.

As discussed above the particular structure, i.e., the size, shape and porosity, of the electrode distal tip 60 is of particular importance to the functioning of the pacing lead 20, and the cardiac pacemaker system. The grooves 62 provide a means for capturing blood born cells during implant of the pacing lead. Specifically, the grooves 62 in the electrode distal tip 60 as illustrated herein, provide a capture site for blood cells and elements therein, including platelets, thrombin, red blood cells, and other elements, and the initiation of the formation of blood clotting upon insertion of the electrode assembly 36 into the vein of the recipient. As the lead body 22 of the pacing lead 20 is fed into the vein of the recipient, and the electrode assembly 36 proceeds to the heart, the platelets, thrombin, red blood cells, and other blood borne elements which are captured within the grooves 62 begin to form a thrombosis or blood clot. This blood clot, upon contact with the endocardial tissue, helps assist in affixing the electrode distal tip 60 to the endocardial tissue, to provide immediate stabilisation of the electrode to endocardial tissue. The grooves 62 also help to capture some amount of the soft, mouldable endocardial tissue to assist also in immediately

stabilising the electrode tip.

It is anticipated that the grooves 62, while relatively shallow, will capture enough platelets, red blood cells, and other elements and endocardial tissue during the passage from the venous insertion point to the endocardium of the heart, generally to fill a majority of the recessed area. Accordingly, for a lead's electrode distal tip 60 having a diameter of between one and four millimeters, and a preferred diameter of two millimeters, and a preferred diameter of two millimeters, the grooves 62 will have a depth in the range of between 0.1 and 0.5 millimeters and a width of between about 0.2 and 1.0 millimeters; and preferably, about 0.4 and 0.4 millimeters, respectively. Further, it is preferred that the edges of the grooves 62 be radiused in order to minimise tissue damages.

The electrode distal tip 60 is also treated to increase the porosity and active surface area, thereby enhancing the electrical efficiency by lowering the polarisation and increasing capacitance. This texturing treatment of the electrode distal tip 60 includes depositing generally spherical shaped small particles on the surface of the electrode distal tip 60, including all the surfaces defining the grooves 62 as well as the plateaux 64. These generally spherical particles 70 are illustrated in the electron microscope photograph views shown in Figures 4 and 5 in greater detail.

Preferably, the conductive electrode 50 is made of a platinum-iridium composition. In the preferred embodiment, the platinum-iridium alloy has a composition of 90% platinum, 10% iridium by weight. The generally spherical particles 70 are preferably platinum/iridium (90%/100%) particles having a generally smooth surfaced spheroidal shape. It should be recognised however, that the electrode and the particles may be made of other suitable materials, such as titanium. The diameters of the spherical particles 70 should be in the range of between about 20 and 200 μm (0.1mm to 0.20mm), and preferably be in the range of between 20 and 80 μm (0.02mm to 0.08mm). Additionally, it is preferred that the spherical particles have a distribution of sizes spanning this range. Preferentially, two coatings of the spheroidal particles are applied to the base electrode. The first coating is preferred to be of particles in the range of 40-80 μm and the second coating 20-40 μm .

Upon affixation to the electrode distal tip 60, the generally spheroidal particles 70 will create a plurality of pore sites and interstitial porosity for chronic ingrowth of tissue. Preferably, the affixation of the spheroidal particles 70 having the preferred sizes and distribution of size, the interstitial porosity defined by the multiple layers of spheroidal particles 70 will have passageway dimensions which allow the passage of red blood cells (typically having a six μm (0.006mm) diameter) and other blood borne elements. By allowing the migration of red blood cells and other blood carried substances through the inter-

stitial porosity, the events resulting in chronic tissue ingrowth are initiated.

The spheroidal particles 70 preferably have a generally smooth surface in order to minimise the amount of irritation of the endocardial tissue caused by the electrode distal tip 60 during the continuous beating of the heart. In addition to providing interstitial porosity for tissue ingrowth, the affixation of the spherical particles 70 also substantially increases the true surface areas of the electrode distal tip 60. Generally, by use of these spheroidal particles 70, the true surface area of the electrode distal tip 60 is increased by as much as a factor of five to twenty times.

Following affixation of the spherical particles 70 to the electrode distal tip 60, the electrode distal tip 60 and the particles 70 are treated with a surface coating means for increasing the active electrical surface area and enhancing the electrical efficiency by reducing the degree of electrochemical polarisation and increasing the electrical capacitance of the electrode distal tip 60 during operation of the pacemaker system. Preferably, a nonmetallic material such as titanium nitride is used as the surface coating, as shown in the electron microscope photograph of Figure 6. In the electron microscope photograph of Figure 6, a portion of the surface of the electrode distal tip 60 is enlarged by a factor of eight thousand. As may be appreciated from observing this photograph, the surface coating further increases the true surface area of the electrode distal tip 60 by a significant factor.

In addition to increasing the true surface area, the surface coating substantially enhances the electrical characteristics of the electrode distal tip 60. The surface coating increases the electrode's electrical capacitance and lowers the polarisation developed at the electrode distal tip 60. It should also be noted that the surface coating on the spherical particles 70, while appearing to create relatively sharp edges thereon, does not result in irritation to the endocardial tissue because the relative size of the crystalline structure of the surface coating is substantially smaller than the heart's cells, the other cardiovascular tissue, and the blood elements which the coating will contact (i.e., red blood cells having an approximate diameter of six microns).

The surface coating is deposited in a manner such that the thickness of the surface coating attached to the spherical particles 70 is in a range of between one to thirty μm . While titanium nitride is the preferred surface coating material, other suitable nonmetallic coating materials, such as, for example, carbon, iridium oxide, and titanium oxide; and platinum oxide may also be applied as the surface coating of the electrode distal tip 60 following affixation of the spherical particles 70.

Figure 7 is a graph depicting the generalised pacing threshold performance of an electrode constructed according to the present invention. In Figure 7, the

pacing threshold energy of microjoules is depicted on the Y-axis as a function of time, in weeks, along the X-axis, for two exemplary lead designs of the prior art and the lead 20 according to the present invention. In the graph, the average energy threshold is based upon voltage thresholds at various pulse durations and assumes pacing impedance remains generally constant. As depicted, the increase in the average energy requirement within the four to six weeks following implant is substantial for the pacing leads of the prior art. By comparison, the lead 20 of the present invention exhibits virtually no threshold increase, and remains relatively level at a lower average energy than either of the prior art leads. As may be appreciated, this will result in an increased threshold safety margin and/or a substantial increase in the useful life of the pacemaker system, given a fixed battery capacity, since the required energy to stimulate the heart is low.

Figure 8 graphically depicts the improved cardiac signal sensing capability of the electrode design of the present invention. In Figure 8 the cardiac signal amplitude in millivolts is depicted on the Y-axis as a function of time (in weeks) on the X-axis, for the lead of the present invention and a lead according to the prior art. As depicted, the lead of the present invention maintains a relatively uniform high level for the cardiac signal amplitude, as compared to the prior lead which has both a lower initial level and a reduction over the course of the first two to three weeks. The primary difference reduced as a result of the significantly reduced polarisation of the lead of the present invention, as discussed in greater detail below.

Figures 9 and 10 are a cross-sectional view and an end view of an alternative embodiment of the distal tip of an electrode 80 for the electrode assembly 36. The electrode distal tip 80 includes a plurality of generally parallel grooves 82 defining therebetween generally parallel strip plateaux sections 84. In the embodiment shown, three grooves 82 are illustrated; however, it should be understood that a limited number of additional grooves may be incorporated. The number of the grooves 82 is limited by the size of the grooves appropriate for the capture of platelets, red blood cells, and other blood elements and tissue as described above, and the diameter of the electrode distal tip 80. In the preferred configuration, the diameter of the electrode distal tip 80 will be in the range of one to four millimeters. Preferably, the diameter of the electrode distal tip 80 is approximately two millimeters.

Figures 11 and 12 are a cross-sectional view and an end view respectively of a second alternative embodiment of an electrode distal tip 90 for the electrode assembly 36. This embodiment includes a plurality of intersecting grooves 92 which define therebetween generally square shaped plateaux 94. Alternatively the plateaux may be round in shape as shown by ref-

erence numerals 95. As above, the grooves 92 are dimensioned so as to allow capture of platelets, red blood cells, and other blood elements during insertion of the lead 20 into the patient. In addition, as shown in Figure 11, the grooves 92 are cut into the electrode distal tip 90 such that a base 96 of the grooves, when viewed in cross-section, defines a part hemispherical inner surface. Thus, in Figures 11 and 12, both the surfaces of the plateaux 94 and the base 96 of the grooves 92 define part hemispherical base surface configuration can also be incorporated into the designs illustrated in Figures 2 and 3, as well as in the design of Figures 9 and 10.

An additional alternative design configuration which may be incorporated into any of the three embodiments shown in Figures 2 and 3, 9 and 10, or 11 and 12, is shown in Figure 13. Here, the base of the grooves 102 is illustrated as either having a flat surface 104 or a concave inner surface 106. Thus, in any of the electrode distal tip configurations of the present invention, it is contemplated that the base of the groove or grooves may define a concave base surface, a flat base surface may define a concave base surface, a flat base surface or part spherical base surface profile.

Additionally, while it has been illustrated in the figures that the walls 108 (Figure 13) defining the grooves of the embodiments have generally flat surfaces which are parallel to the axis of the distal tip, it will be appreciated that the walls of the grooves may be generally angled with respect to the axis of the distal tip. In addition, the corners at the base and the peaks of the grooves for any of the above described embodiments may be radiused to a radius of curvature of between about 0.001mm and 0.5mm, as opposed to having sharp edges. The grooves of any of the above embodiments may be formed by any of the methods selected from the group including stamping, milling, moulding and electrochemical machining. The generally spherical particles 70 which are applied to the surfaces of the electrode distal tip 60 as discussed above with respect to Figure 1 are also applied to the alternative embodiments as is the titanium nitride or alternative surface coating treatment. The spherical particles 70 are preferably attached to the surfaces of the electrode distal tip by a process such as sintering, laser fusion or welding, injection and moulding casting.

Finally, the surface coating of titanium nitride or alternative material, is applied to the spherical particles 70 of the electrode distal tips 60 or any of the alternative embodiments by a process such as sintering in an appropriate environment, vapour deposition, electroplating and sputtering.

The surface coating is illustrated in Figures 14 and 15 which schematically depict top and side views respectively of the microporous surface structure. Figure 14 illustrates the generally pyramid-like shape

of the microporous coating. In Figure 15, a side or profile view of the microporous surface coating illustrates the triangular peaks of the coating, and more importantly the areas between the peaks of the coating which provide high surface porosity. With the foregoing construction, incorporating the microporous surface coating, the surface porosity or microporosity is in excess of fifty percent (50%), and preferably in the range of between sixty-five percent (65%) and seventy percent (70%).

A pacing lead having an electrode tip configured in accordance with the foregoing detailed description exhibits superior pacing performance. The primary reason for the superior performance is the reduction in polarisation proximate the electrode tip. The "polarisation voltage" for a pacing lead is herein defined to be the voltage differential developed between the leading edge and the trailing edge of a reference electrical impulse. The reference electrical impulse is a 10 mA (milliampere), one millisecond, square wave, constant current pulse from a pulse generator. The polarisation voltage (Pv) for a particular pacing lead is determined by subtracting the leading edge voltage (V1), from the trailing edge voltage (V2) of the reference electrical impulse ($Pv = V2 - V1$). During measurement of the polarisation voltage, the electrode is immersed in a 0.15 molar sodium chloride (NaCl) solution, at a pH of 7, and temperature of 37°C.

As may be appreciated by those skilled in the art, the polarisation voltage measured according to the above test will be influenced substantially by the size, shape, material, and surface nature of the electrode distal tip for a given pacing lead. Thus, for an electrode distal tip having a particular profile, and made of a particular material having a particular surface nature, the polarisation voltages will be different for a 3mm² tip and a 5mm² tip. Conversely, two pacing leads having 5mm² electrode tips will have characterising polarisation voltages which will depend on their particular profile, construction, material and surface nature. Generally the pacing lead electrode which has a lower polarisation voltage for any given electrode design, or more simply the circumferential area, (cross-sectional area for a non-round tip) will be the more desirable pacing lead.

Accordingly, to further characterise pacing lead electrodes and more particularly the pacing lead of the present invention, a "polarisation index" (PI) is herein defined. The polarisation index is the polarisation voltage Pv divided by the circumferential area CA (or cross-sectional area) of the electrode at its widest diameter. Thus, for a semi-spherical electrode having a diameter "d," the circumferential area CA is equal to $\pi (d/2)^2$, and the polarisation index is given by the following formula:

$$PI = (V2 - V1) / \pi (d/2)^2 \text{ or } PI = Pv/CA$$

The pacing leads of the present invention as disclosed in detail above have a polarisation index PI

which is less than 100mV/mm². More particularly, in the preferred embodiments, the pacing leads of the present invention have a polarisation index PI which is less than 50mV/mm². A pacing lead having an electrode tip which combines a surface morphology allowing tissue ingrowth and very low polarisation index levels is highly desirable in the field of implantable cardiac pacing leads.

It should be evident from the foregoing description that the present invention provides many advantages over pacing leads of the prior art.

Claims

1. An implantable lead (20) for use with a cardiac pacemaker comprising an electrical conductor having an outer insulating sheath (24), an electrical connector (28) coupled to the proximal end of the conductor and an electrode (36) coupled to the distal end of the conductor, characterised in that the electrode (26) has an electrode tip (60) macrostructure geometry defining at least two plateau sections (64) separated and the recessed groove section (62) including surfaces having affixed thereto at least one layer of generally spheroidal conductive particles (70) coated with a layer of nonmetallic material.
2. A lead as claimed in Claim 1, characterised in that the conductive particles (70) have diameters ranging from 10 to 200 μm , and are configured in at least one layer on the electrode surfaces to provide interstitial porosity for tissue ingrowth.
3. A lead as claimed in Claim 1 or Claim 2, characterised in that the conductive particles (70) are formed of platinum, titanium, palladium, platinum-iridium or carbon.
4. A lead as claimed in any preceding Claim, characterised in that the conductive particles (70) are affixed by a powder sintering process which preferably comprises a series of two to five steps, a proportion of the particles being affixed in successive steps.
5. A lead as claimed in any preceding Claim, characterised in that the interstitial porosity areas between the conductive particles (70) have a plurality of passage diameters greater than six μm to allow the passage of blood cells.
6. A lead as claimed in any preceding Claim, characterised in that the electrode tip includes two recessed areas (62) configured to intersect one another thereby defining a cross shape; or includes at least two parallel aligned recessed areas (82) defining at least three generally aligned plateau areas (84), the corners of these plateau areas such defining an angle of at least sixty degrees, or includes at least two sets of multiple, parallel aligned, recessed areas (92), configured to have the multiple aligned recessed areas of the sets intersecting one another.
7. A lead as claimed in any preceding Claim, characterised in that the recessed groove section (62,82,92) has a profile defined by a depth of between 0.1 and 1.0 millimetres, a width of between about 0.2 and 1.5 millimetres, and each edge of the groove is optionally radiused with a radius of curvature of between about 0.001 and 0.5 millimetres.
8. A lead as claimed in any preceding Claim, characterised in that the non-metallic material is titanium nitride, iridium oxide, titanium oxide, platinum oxide, palladium oxide or an activated form of carbon.
9. A lead as claimed in any preceding Claim, characterised in that the layer of non-metallic material has a surface morphology which results in a porosity of greater than about fifty percent.
10. A lead as claimed in any preceding Claim, characterised in that the electrode (36) has a distal tip and a polarisation index PI which is less than 100mV/mm² and preferably less than 50mV/mm².
11. A method of forming an implantable lead (20) for use with a cardiac pacemaker which comprises covering an electrical conductor in an insulative sheath (24), coupling an electrical connector (28) to the proximal end of the conductor and coupling an electrode (36) to the distal end of conductor, characterised by: forming the electrode tip (60) macrostructure geometry to define at least two plateau sections (64) separated by at least one recessed groove section (62); affixing to the plateau sections (64) and the recessed groove section (62) a plurality of generally spherical conductive particles (70); and coating the particles (70) with a layer of non-metallic material preferably selected from titanium nitride, palladium, platinum oxide, iridium oxide, and activated carbon.
12. A method as claimed in Claim 11, characterised in that the conductive particles (70) are coated by vapour deposition, sintering, electroplating and electrode sputtering, preferably to a thickness of 20 to 30 μm .
13. A method as claimed in Claim 11 or Claim 12,

characterised in that the conductive particles (70) are affixed to the electrode distal tip (60) by powder sintering, laser fusion, welding, injection moulding, or casting.

5

14. A method as claimed in any of Claims 11 to 13, characterised in that the conductive particles (70) are affixed in a series of successive steps in which a portion of the particles are affixed in each successive step.

10

15

20

25

30

35

40

45

50

55

10

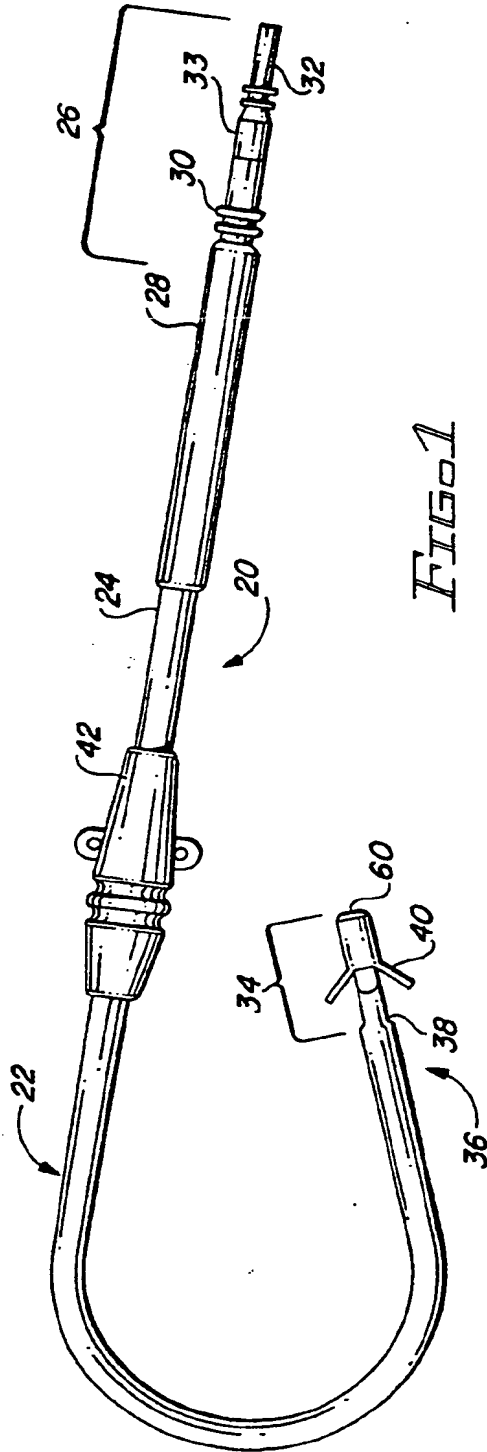


FIG 1

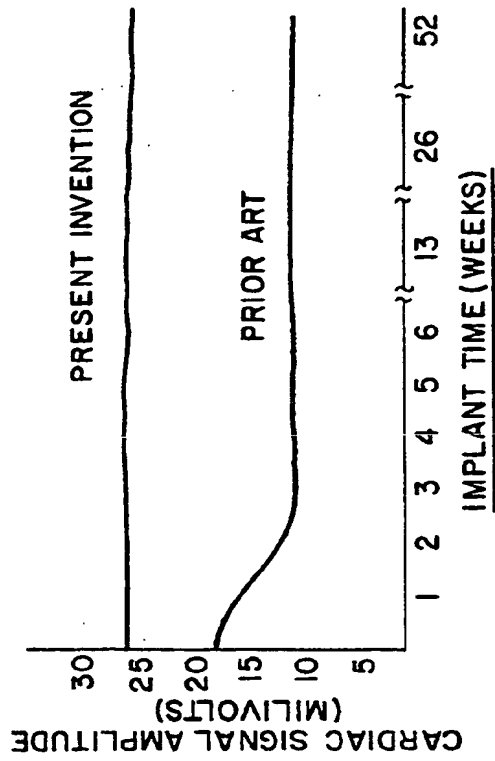


FIG 8

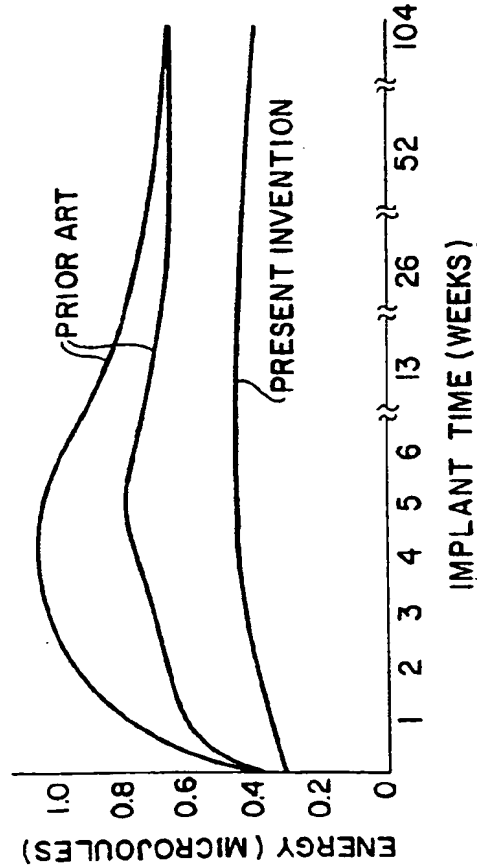


FIG 7

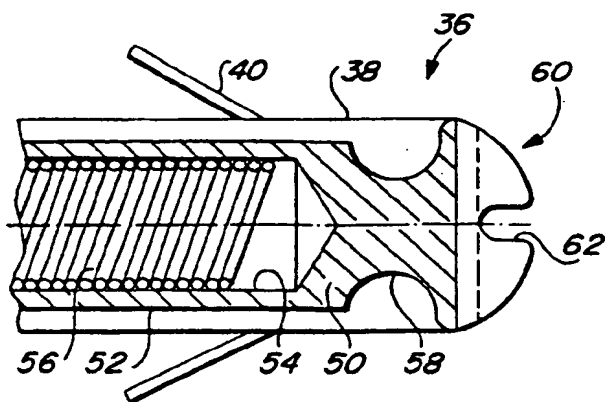


FIG. 2

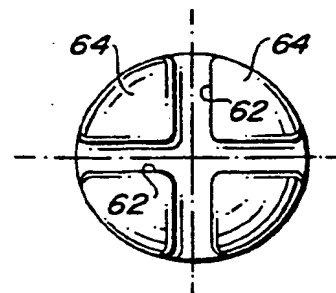


FIG. 3

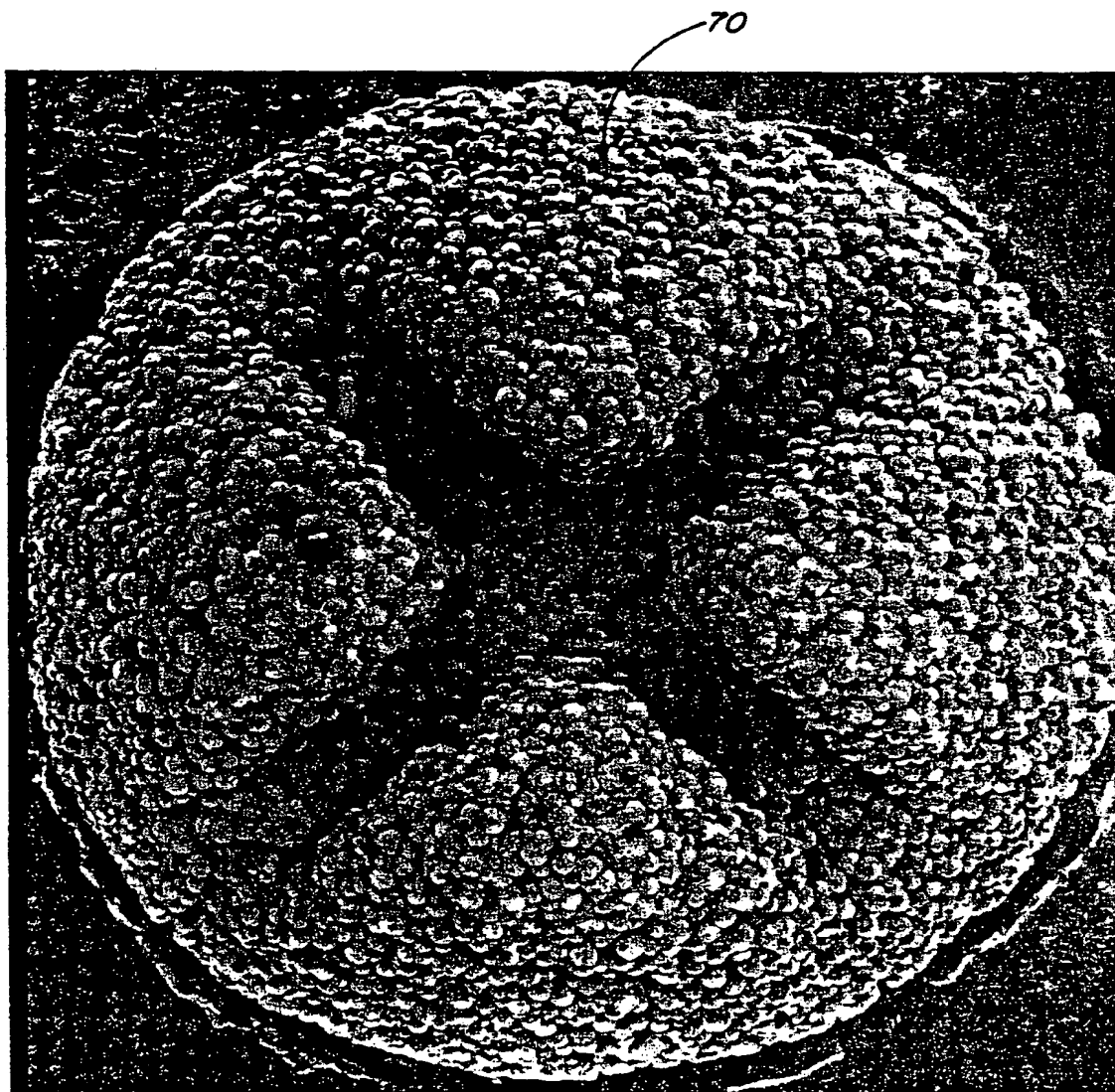


FIG. 4

FIG. 5

70

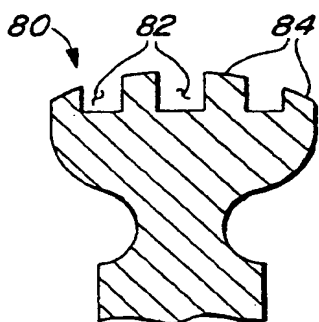
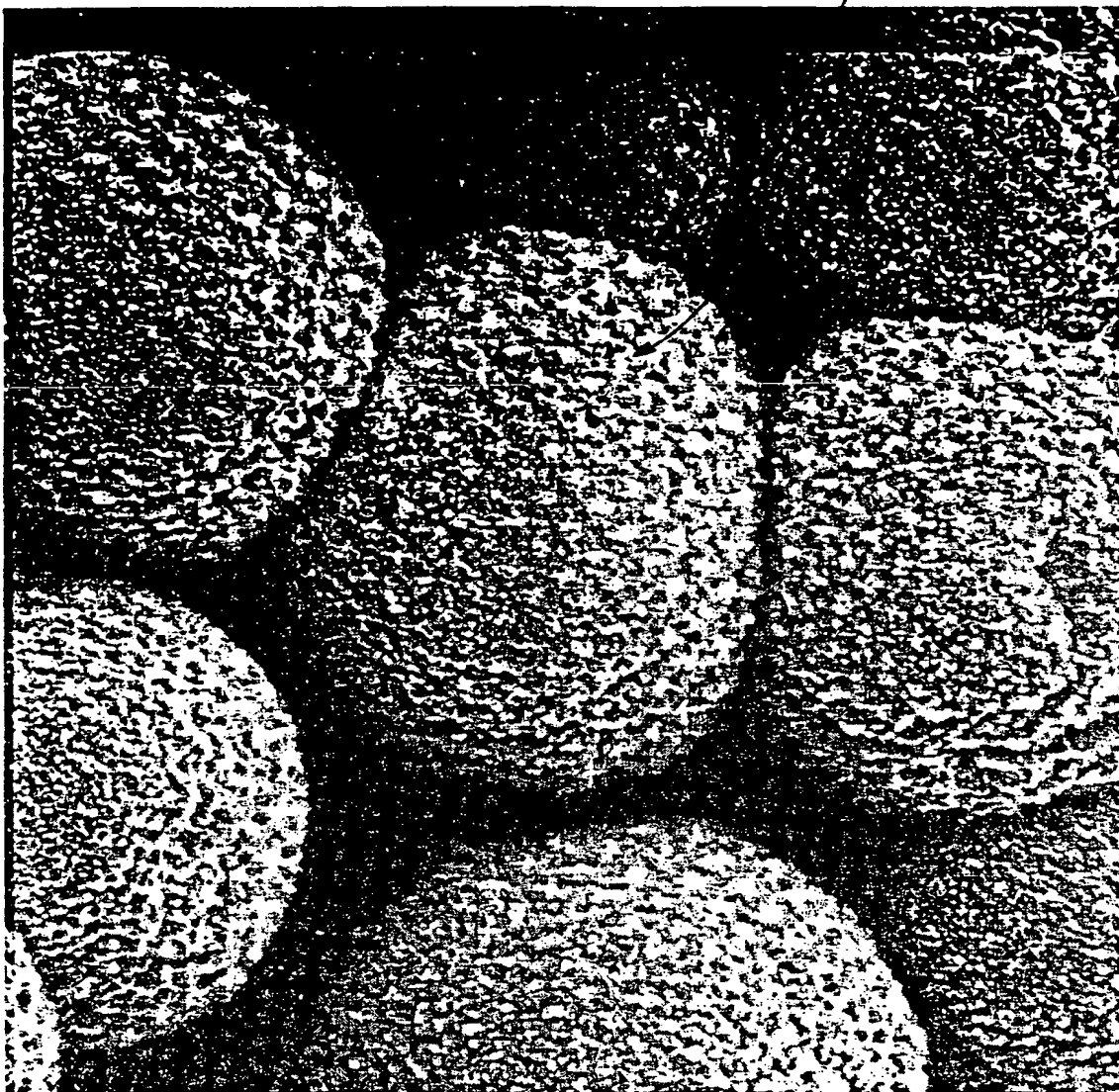


FIG. 9

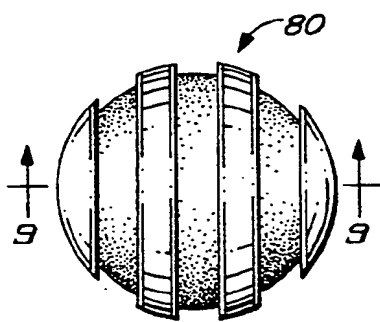


FIG. 10

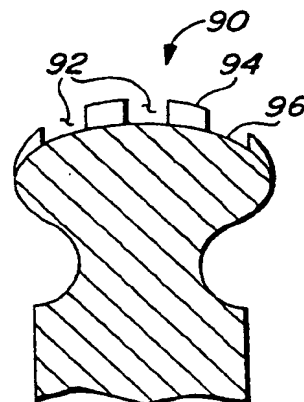


FIG. 11

FIG. 6

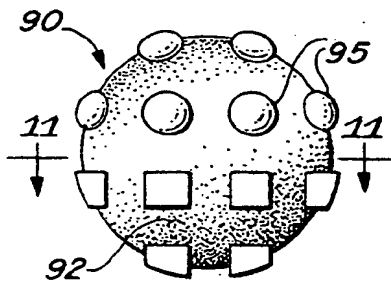


FIG. 12

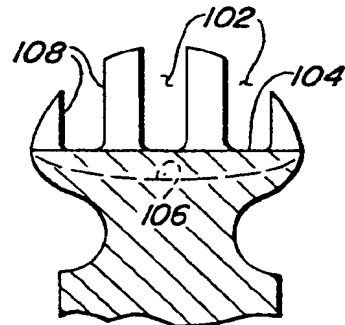


FIG. 13



FIG. 14



FIG. 15



⑪ Publication number : **0 573 275 A3**

⑫ **EUROPEAN PATENT APPLICATION**

⑲ Application number : **93304272.3**

⑤① Int. Cl.⁵ : **A61N 1/05**

⑳ Date of filing : **02.06.93**

③① Priority : **02.06.92 US 892463**

④③ Date of publication of application :
08.12.93 Bulletin 93/49

⑧④ Designated Contracting States :
CH DE DK FR GB IT LI NL SE

⑧⑧ Date of deferred publication of search report :
25.05.94 Bulletin 94/21

⑦① Applicant : **SIEMENS AKTIENGESELLSCHAFT**
St Martin Strasse 76
D-81541 München 2 (DE)

⑦② Inventor : **Helland, John R.**
22706 Coral Way
Santa Clarita, CA 91350 (US)
Inventor : **Muff, Diane F.**
10618 Dempsey Avenue
Granada Hills, CA 91344 (US)

⑦④ Representative : **Rees, David Christopher et al**
Kilburn & Strode
30 John Street
London WC1N 2DD (GB)

⑤④ **High efficiency tissue stimulating and signal sensing electrode.**

⑤⑦ A pacing lead (20) having a porous electrode of platinum-iridium with recessed areas of grooves (62) formed in the surface. The grooves (62) allow for acute electrode stabilisation as a result of clot formation and endocardial tissue capture during insertion and immediate immobilisation upon implant. At least one layer of porous coating of 20 to 200 μ m diameter spherical particles (70) is deposited on the surface of the base electrode (36) to obtain a porous macrostructure form promoting chronic tissue ingrowth. Additionally, a microstructure surface coating is applied to increase the active surface area and enhance electrical efficiency by lowering electrochemical polarisation and increasing electrical capacitance.

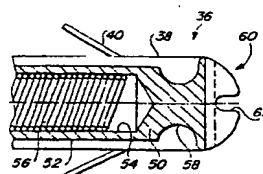


FIG. 2

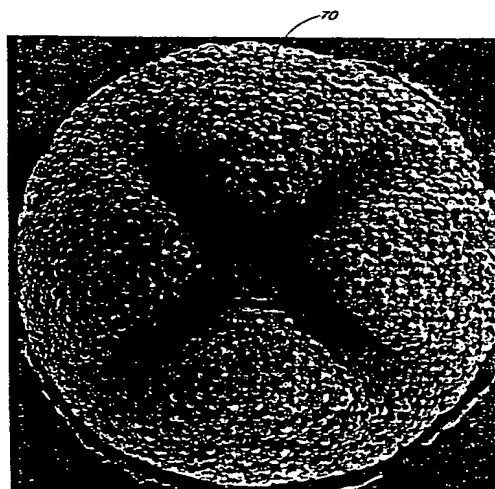


FIG. 4

EP 0 573 275 A3



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 4272

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
Y	US-A-4 649 937 (DEHAAN, JONES, KRUG) * column 3, line 25 - column 6, line 61; figures 1-3 *	1	A61N1/05
A		3, 6-8, 11, 12	
Y	US-A-5 097 843 (SOUKUP, KREYEN HAGEN) * column 4, line 55 - column 9, line 2; figures 1-8 *	1	
A		2-4, 11, 13	
A	FR-A-2 607 013 (TELECTRONICS) * page 14, line 23 - page 16, line 1; figures 14-17 *	1, 6, 11	A61N
A	US-A-4 280 514 (MACGREGOR) * column 2, line 13 - column 3, line 37; figures 1-4 *	1, 2, 11	
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 21 March 1994	Examiner Herbelet, J.C.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		I : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EPO FORM 1503 (03.92) (P04C01)